Before the
FEDERAL COMMUNICATIONS COMMISSION
Washington, D.C. 20554

In the Matter of	)	
	)	
Amendment of Parts 2 and	)	WT Docket No. 99-66
95 of the Commission's Rules	)	RM No. 9157
To Establish the Medical Implant	)	
Communications Service in the	)	
402 - 405 MHz band	)	

To: The Commission

COMMENTS OF MEDTRONIC, INC.

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SUMMARY

The Medical Implant Communications Service ("MICS"), would be a private, ultra-low power mobile radio service for the purpose of transmitting non-voice data in support of diagnostic, monitoring, and/or therapeutic functions associated with implanted medical devices. MICS would permit physicians and their patients to take advantage of the benefits of wireless technology to improve the medical care and capabilities of implanted medical devices and to improve these patient's quality of life.

The need for such a service is great. The current technology used for communications between medical implants and the devices used to program, monitor and control them is dated and severely restricts the capabilities of existing implant technologies. The current system increases the risk of infection to patients, requires patients to endure uncomfortable positions, and limits the actions of medical personnel working with the equipment. In addition, the slow data exchange rate prohibits the exploitation of new developments in implant technology.

The use of the 402-405 MHz band is essential to the medical success of MICS. Given the technical requirements of MICS (size, power, antenna performance, and receiver design), the 402-405 MHz band fully satisfies those requirements. In addition, the characteristics and worldwide availability of this band fully satisfies the medical requirements of MICS.

There is no question that the adoption of MICS is in the public interest. Medtronic supports the Commission's proposal to create this service and proposes minor rule changes to reflect recent developments in technology and to preserve service flexibility. Additionally, Medtronic encourages the Commission to act promptly on MICS so that its benefits can be quickly brought to those people who rely upon implants for the gift of life.

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To: The Commission

COMMENTS OF MEDTRONIC, INC.

Medtronic, Inc. ("Medtronic"),[1] by its attorneys, hereby submits these comments in support of the Commission's proposal to create the Medical Implant Communications Service ("MICS") in the 402-405 MHz band.[2] MICS would be a private, ultra-low power mobile radio service for the purpose of transmitting non-voice data in support of diagnostic, monitoring, and/or therapeutic functions associated with implanted medical devices. Because this service will yield significant public interest benefits, Medtronic continues to urge the creation of MICS and recommends some minor changes to the proposed rules to reflect technological and international regulatory developments that have transpired since the service was first proposed.

[1] Medtronic, established in 1949, is a world leader in medical implant technology. It conducts business in 120 countries and manufactures medical implants that regulate heart rates, control pain, improve motor functions and administer medication, among other things.

[2] *See* Amendment of Parts 2 and 95 of the Commission's Rules To Establish a Medical Implant Communications Service in the 402-405 MHz Band, WT Docket No. 99-66, RM No. 9157, *Notice of Proposed Rulemaking*, FCC 99-23 (rel. Feb. 24, 1999) ("*MICS NPRM*").

I. MICS ADVANCES THE PUBLIC INTEREST BY ALLOWING MEDICAL IMPLANTS TO TAKE ADVANTAGE OF THE DEVELOPMENTS IN WIRELESS COMMUNICATIONS

As Medtronic pointed out in its Petition for Rulemaking, MICS would greatly improve the utility of medical implants and enhance the quality of life of patients by permitting such devices to take advantage of the benefits wrought by high speed, easy-to-use, reliable, short-range, wireless communications links.[3] Equipment designed, developed and manufactured under this new service would provide a more efficient and less invasive method to manage implanted devices and acquire diagnostic data than the inductive systems currently used.[4] Thus, Medtronic wholeheartedly agrees with the Commission's conclusion that the creation of such a service "would further the public interest by promoting a significant advancement in communications with implanted medical devices in a manner that would be far more efficient than now experienced in current systems."[5]

A. The Current Communications System is Dated and Severely Restricts the Capabilities of Existing Implant Technologies

The communications system currently used between implants and the devices used to program, monitor, and control them is dated and severely restricts the capabilities of the implant devices used today. The existing communications technology, which has been in use for many years now, uses magnetically coupled coils to provide the data exchange link between the medical implant inside the patient and the equipment used to control and monitor the implant outside the patient (the "programming device"). Because the communications link is inductively produced, the current technology requires physicians to place the programming head directly on or next to the skin of the

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[3] *See* Petition for Rulemaking at 1 (filed July 28, 1997) ("*Petition*").

[4] *See id.*

[5] *MICS NPRM* at ¶ 7.

patient as close to the implant as possible in order to establish the communications link. Further, the nature of the link is quite delicate so that that movement by the patient can break the communications link. As Medtronic pointed out in its *Petition*, the nature of the link increases the risk of infection during and after implantation, limits the mobility of medical personnel while establishing the link, and requires constant monitoring by trained personnel during the data transfer.[6] In addition, the use of an inductive link can be painful for a patient if the communications device is placed on fresh incisions and/or requires them to remain motionless in uncomfortable positions for a prolonged period of time.[7] What is worse is the fact that the patient is exposed to these problems during the entire useful life of the device, from the moment it is implanted continuing through routine check-ups usually every three to twelve months.

In addition, the existing communications technology limits the data exchange rate to that of about two kilobits per second, which is extremely slow given today's technologies. Therefore, not only will a patient be required to remain immobile in an uncomfortable or painful position in the first instance, but they will remain in that position longer than today's technology would require. Moreover, the slow data exchange rate prevents the devices from taking advantage of the rapid developments in the miniaturization of storage capacity. Without a corresponding change in the data exchange rate, increases in storage of data within an implant would require even longer periods during which the patient would need to remain immobile in order to preserve the integrity of the data link.

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[6] *Petition* at 3-4.

[7] *Id.*

B. Wireless Communications Will Allow Physicians and Patients To Take Advantage of the Full Capabilities of Newer Technologies and Techniques

The solutions to the aforementioned problems lie in the development of communications systems that would allow physicians, or even patients, to establish and maintain painless and sterile communications links. The MICS wireless systems to be implemented under the regulations proposed by the Commission stand out as such solutions.[8] The two key attributes of such new wireless systems would be (1) a minimum operating range of two meters and (2) high data rate transmission capacity (e.g. a 100 kilobit/second rate for implant to programming device communications).

In short, the creation of MICS would resolve many of the limitations associated with the current inductive technology described in the previous section. First, a wireless system would not require the positioning of the programming head immediately next to the skin of the patient. Instead, the programming device could be positioned away from the implant wound. In addition, the patient would no longer be required to remain motionless and in an uncomfortable or painful position to maintain the integrity of the link. In fact, the physician could perform other tasks with the patient while the communications link is operating, making doctor visits more productive and efficient. Second, the increased data rate exchange would allow physicians and manufacturers to utilize the ever increasing capacity of devices to store information. Increased amounts of storage capacity could reduce the number of required post-operative visits by a patient because the device could store more information, making each visit more productive. Also, the higher exchange rate would also reduce the time the communications link is operating, further shortening visits.

The use of a wireless communications system to link implanted devices with diagnostic equipment would also improve the manner by which other types of patient monitoring are

accomplished in addition to the diagnostic and/or therapeutic functions traditionally associated with implants. For example, wireless links, given their more robust nature, would give doctors and patients the ability to perform monitoring functions from a bedside monitoring device. In one scenario, a bedside device could automatically monitor the status of an implant patient and transmit the data (via phone line, for instance) to the physician. In another scenario, implantable hemodynamic monitors ("IHMs") that measure physiologic parameters from within the body could be implanted in patients that repeatedly enter the cardiac care unit, such as those with congestive heart failure and other similar diseases. This device could provide CCU staff with real time access to parameters whenever it is activated – without the need for the patient to undergo painful, expensive, and potentially dangerous catheterizations. Further, a similar type of monitoring could now be accomplished from the home setting, thereby allowing for improved care and reduced costs.

II. THE USE OF THE 402-405 MHZ BAND IS ESSENTIAL TO THE MEDICAL SUCCESS OF MICS

The technical and functional requirements of MICS – power consumption, size, receiver design, and antenna performance – make the choice of spectrum critical to the success of MICS. When it began searching for appropriate spectrum, Medtronic examined the aforementioned requirements, checked the international regulations, and consulted with the appropriate authorities. In the end, Medtronic determined that the 402-405 MHz band appears to be the only

(...Continued)

[8] *See MICS NPRM*, at ¶ 16.

viable spectrum option and recommended its assignment, on a secondary basis, to MICS.[9] Therefore, Medtronic agrees with the Commission's conclusion to locate MICS in this band.[10]

A. The 402-405 MHz Band Satisfies the Technical Requirements of MICS

The solutions to the four technical concerns – power, size, receiver design, and antenna performance – presented by the unique operating environment of medical implants act to restrict the type of spectrum that can be used for MICS.

Power Consumption. Power consumption is a critical factor for medical implants. Implants have a limited power source that must be conserved and managed to last for the life of the patient or the implant.[11] Power sources cannot be easily replaced because the procedure for replacing an implanted medical device is both expensive and carries surgical risks. When a device is transmitting, the implant must radiate enough power, at the expense of battery life, to overcome natural and man-made interference. This interference decreases as frequency increases. Yet, there is a cost to higher frequencies because power consumption increases with frequency. Therefore, operation in any frequency band above 450 MHz would consume far more power than is acceptable.

Size. Clearly, size is a very important consideration for implanted medical devices. This fact is particularly true because these devices are also used in children. The size of the device can be reduced by exploiting surface acoustic wave ("SAW") components for the implant receiver's preselector filter and integrated circuits for other filter functions. These SAW components

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[9] *See Petition* at 7-8.

[10] *See MICS NPRM* at ¶ 16.

[11] This fact also pushes the system designers to minimize the amount of time devoted to communications.

perform particularly well in frequencies between a few hundred megahertz and a gigahertz. Also, the size of the SAW component increases as frequency decreases. Thus, given the power constraints discussed above, important size requirements can be met if the frequency of operation ranges between 250 and 450 MHz.

Receiver Design. The power consumption and size constraints make it difficult to design a receiver that handles interference well. The implant receiver's dynamic range is limited by the device's target power consumption of less than 5 mW. The relatively poor dynamic range eliminates the option of operating these devices at frequencies near those allocated to high power transmitters such as broadcast television. In the United States, this constraint limits operations of the receiver to between 216 and 470 MHz. Further, the presence of other systems operating with several orders of magnitude more power than MICS transmitters within a hospital environment pose a potential interference problem if the implant were to operate in the 450 to 470 MHz band. Thus, the optimal spectrum for receiver design is between 216 and 450 MHz.

Antenna Performance. Antenna performance of both the implanted device and the associated programming device also affects the available spectrum options. The antenna performance of the implanted device is severely reduced by the conductivity of bodily tissues and fluids. The reflection at the air-tissue boundary and plane wave attenuation in this media further increase the path loss. Losses due to body tissues and fluids increase with frequency, while on the other hand, losses due to reflection decrease with frequency. The problem is that operation above several hundred MHz introduces more loss into the communications link than can be overcome by a device with a low power budget and operation below 250 MHz introduces more reflection into the communications link than is acceptable.

An additional problem is that the programming device antenna must have reasonable gain at lengths of 30 cm or less in order to ensure that this component is truly portable. Moreover, spatial diversity on the programming device can be used to maintain a reasonable link margin, but this is feasible only if the physical dimensions of the two antennas can be accommodated within a small space. The end result is that the lowest attainable frequency is about 250 MHz, due to implant size constraints while the highest attainable frequency is limited by tissue losses and implant power consumption.

B. The 402 - 405 MHz Band Is the Best Medical Fit

In short, given the technical constraints imposed by the requirements for MICS equipment discussed above, the optimal spectrum lies between 250 and 450 MHz. However, the technical constraints are only one half of the equation. The other set of concerns are those imposed by the medical nature of MICS. These medical concerns point to the fact that the 402-405 MHz band best solves the spectrum needs of MICS.

First, an ability to use greater amounts of storage capacity available to implant devices is necessary in order to take advantage of the developments stemming from the advancements made in medical technology and science. However, in order to utilize this increased storage capacity, it is essential that data exchange rates be much higher than the current rate of two kilobits per second. In order to achieve the ability to dramatically increase the data exchange rate, it is essential that the communications link be established at a higher, comparatively wide bandwidth, which implies a need for wide channels.

Second, given the fact that the communications link between the implant and the programming device will be operating in hospitals and clinics, it will be essential that MICS enjoys enough spectrum so that communications links can be divided into channels. The need for

channels begins with the identification of the optimal uplink, which is about 100 kilobits per second. Then, to support such a bit rate using digital modulation (to reduce interference and data corruption), as Medtronic explained in its *Petition*, the uplink bandwidth must be approximately 300 kHz.[12] Finally, in order to avoid the possibility of multiple programmer units interfering with each other and to allow the system to avoid the many 1 MHz wide interferers that have been measured in clinical environments, MICS will require a number of 300 kHz channels. In order to provide sufficient spectrum to minimize the chance of data corruption resulting from interference, at least ten channels occupying 3 MHz of bandwidth are needed. The amount of bandwidth required in this setting further limits spectrum choices.

Finally, in order for MICS to be truly successful, it must have access to a single, worldwide slice of spectrum of at least 3 MHz in width for use by all beneficiaries of medical implants. Implanted medical devices are portable by design. Patients with such devices travel around the world and can be far from their primary physician if an emergency were to arise and the need to communicate with the implant occurs. This need drastically limits the available spectrum to MICS.

* * * * *

After reviewing all of the available spectrum meeting the requirements discussed above, Medtronic found, and the ITU recommends, that "[o]peration in a portion of the band from 401-406 MHz appears to be the only viable option."[13] In the United States, such operations would be

[12] *See Petition* at 10.

[13] *ITU MICS Recommendation* at § 1.

limited to the 402-405 MHz band, as recommended by the Commission.[14] Further, the ITU also found that "sharing is feasible in the band 401-406 MHz between the Meteorological Aids Systems," the present incumbent, and MICS.[15] Given these results, the best (and only) band that satisfies all of the particular needs and requirements of MICS is the 402-405 MHz band.

III. MEDTRONIC PROPOSES MINOR RULE CHANGES TO REFLECT RECENT DEVELOPMENTS IN TECHNOLOGY AND TO PRESERVE THE FLEXIBILITY THE SERVICE NEEDS

Since filing its Petition for Rule Making in July of 1997, Medtronic has continued to pursue the development of technology designed to support MICS operations. In addition, efforts have begun in Europe, Asia, and the Americas to pave the way for compatible MICS operations so that persons traveling to and from other countries may continue to benefit from MICS systems implemented in their medical implant devices. Appendix A to these Comments sets forth minor revisions to the regulations proposed by the Commission. These recommended changes are designed to clarify equipment certification measurement procedures and facilitate the operation of multiple MICS systems to be developed by various manufacturers. As such, Section 95.630 sets forth the most significant of the recommended revisions by calling for a monitoring capability designed to assure that before a MICS programmer/control transmitter initiates a communications session, a channel with a minimal amount of noise present is employed. This concept, which allows multiple users with differing technologies to share a single band on an equal access basis, has already been implemented in the regulations pertaining to unlicensed PCS systems. The same sort of interference management approach will greatly facilitate the integration of MICS

[14] *See MICS NPRM* at ¶ 16.

[15] *ITU MICS Recommendation* at ¶ 1.

operations into often congested RF environments. Thus, it will assure more interference free MICS operations and promote spectrum efficiency.

IV. CONCLUSION

As demonstrated above, the Commission was correct to find that the new technologies afforded by MICS would greatly improve the utility of medical implant devices by allowing physicians to establish high speed, easy-to-use, reliable, short-range, wireless links to interconnect the implanted medical devices with monitoring equipment."[16] Such a finding demonstrates that establishment of MICS and its assignment of spectrum in the 402-405 MHz band is most certainly in the public interest. With the adoption of the Commission's proposed rules, as modified by the changes suggested above, the Commission will find that this service will indeed provide "a safer, less expensive, and less invasive method to diagnose and manage patient conditions" than today's technology.[17] Accordingly, Medtronic urges the Commission to

[16] *MICS NPRM* at ¶ 7.

[17] *MICS NPRM* at ¶ 7 (footnote omitted).

act expeditiously to adopt rules that will help to make the Medical Implant Communications System a reality.

Respectfully submitted,

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APPENDIX ~~B~~ A - PROPOSED RULES
Recommended Revisions Shown as Underlined Text

Parts 2 and 95 of Title 47 of the Code of Federal Regulations are proposed to be amended as follows:

PART 2 - FREQUENCY ALLOCATIONS AND RADIO TREATY MATTERS; GENERAL RULES AND REGULATIONS

1. The authority citation for Part 2 continues to read as follows:

Authority: 47 U.S.C. 154, 302, 303, 307 and 336, unless otherwise noted.

2. In Section 2.106, the Table of Frequency Allocations is amended by revising the entries for the 402-403 and 403-406 MHz bands by adding the Medical Implant Communications Service (MICS) in the Non-Government 402-403 MHz and 403-406 MHz bands, and adding Non-Government footnote NG156 to read as follows:

§ 2.106 Table of Frequency Allocations

* * * * *

International table			United States table		FCC use designators	
Region 1 -- allocation MHz	Region 2 -- allocation MHz	Region 3 -- allocation MHz	Government	Non-Government	Rule part(s)	Special-use frequencies
(1)	(2)	(3)	Allocation MHz (4)	Allocation MHz (5)	(6)	(7)
*	*	*	*	*	*	*
402-403	* * *		402-403 * * * * *	402-403 * * * * * Mobile US70 NG156	PERSONAL (95)	402-403 Medical Implant Communications (MICS)
403-406	* * *		403-406 * * * * *	403-406 * * * * * Mobile US70 NG156	PERSONAL (95)	403-405 Medical Implant Communications (MICS)

* * * * *

NG156 Medical Implant Communications Service (MICS) stations are authorized by rule on the conditions that harmful interference is not caused to stations in the Meteorological Aids, Meteorological Satellite, and Earth Exploration Satellite Services and that MICS stations accept interference from stations in the Meteorological Aids, Meteorological Satellite, and Earth Exploration Satellite Services. Certain MICS stations are subject to the registration requirements set forth in Section 95.1115 of this Chapter.

3. ~~3.~~ Section ~~2.1204~~ 2.1202 is amended by adding paragraph ~~(a)(9)~~(f) to read as follows:

§ ~~2.1204 Import conditions.~~ 2.1202 Exclusions

* 1 moved from here; text not shown

~~(a) * * *~~
~~(9) The~~(f) A radio frequency device that is a medical implant transmitter ~~inserted~~ implanted in a person granted entry into the United States or is a medical implant ~~programmer/controller~~ programmer/control transmitter associated with ~~such~~ an implanted transmitter, provided, however that the transmitters covered by this provision otherwise comply with the technical requirements applicable to transmitters authorized to operate in the Medical Implant Communications Service under Part 95 of this chapter. Such transmitters are permitted to be imported without the issuance of a grant of equipment authorization only for the personal use of the person in whom the medical implant transmitter has been ~~inserted.~~ implanted.

[Rationale: As proposed, Section 2.1204 would have allowed the importation of MICS transmitters implanted in a person and the associated programmer/control transmitter without the grant of equipment authorization, but would have required the user to complete an FCC Form 740 or the electronic equivalent upon entry into the United States. The revised language would delete the requirement for the completion of the Form 740. Upon reflection, Medtronic questions whether the burden of requiring such a record to be created would outweigh the utility of having the record. The revised language is offered so that the Commission can focus more clearly on the burden associated with the paperwork attendant to the importation of such devices under these circumstances. If the Commission ultimately concludes that Form 740 should be completed, then the language as originally proposed should be adopted. In the latter case, however, Medtronic suggests that the word "inserted" be replaced with the term "implanted" in order to conform more closely with accepted medical usage.]

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PART 95 - PERSONAL RADIO SERVICES

4. The authority for Part 95 continues to read as follows:

Authority: Secs. 4, 303, 48 Stat. 1066, 1082, as amended; 47 U.S.C. 154, 303.

5. Section 95.401 is amended by adding paragraph (d) to read as follows:

§ 95.401 (CB Rule 1) What are the Citizens Band Radio Services?

* * * * *

(d) The Medical Implant Communications Service (MICS) - an ultra low power radio service for the transmission of non-voice data for the purpose of facilitating diagnostic and/or therapeutic functions involving implanted medical devices. The rules for this service are contained in subpart H of this part.

6. Section 95.601 is amended by revising the last sentence in the text to read as follows:

§ 95.601 Basis and purpose.

* * * The Personal Radio Services are the GMRS (General Mobile Radio Service)--subpart A, the Family Radio Service (FRS)--subpart B, the R/C (Radio Control Radio Service)--subpart C, the CB (Citizens Band Radio Service)--subpart D, the Low Power Radio Service (LPRS)--subpart G, and the Medical Implant Communications Service (MICS)--subpart H.

7. Section 95.603 is amended by adding paragraph (f) to read as follows:

§ 95.603 Certification required.

* * * * *

(f) Each Medical Implant Communications Service transmitter (a transmitter that operates or is intended to operate in the MICS) must be certificated except for medical implant transmitters that are not marketed for use in the United States, but which otherwise comply with the MICS technical requirements and are operated in the United States by individuals who have traveled to the United States from abroad.

8. Section 95.605 is amended by revising the first paragraph of the text to read as follows:

§ 95.605 Certification procedures.

Any entity may request certification for its transmitter when the transmitter is used in the GMRS, R/C, CB, IVDS, LPRS or MICS following the procedures in part 2 of this chapter. Medical implant transmitters shall be tested for emissions and EIRP limit compliance while enclosed in a medium that simulates ~~the tissue in which the transmitter is to be implanted~~ human body tissue in accordance with the procedures in Section 95.639(f). Frequency stability testing for MICS transmitters shall be performed over the temperature range set forth in § 95.630.

[Rationale: As revised, Section 95.639(f) specifies proposed testing procedures. These procedures would standardize the characteristics of the medium to simulate muscle tissue since a given implant could be in muscle, fat, other tissue, or a combination. Hence, in the interest of reproducibility in the testing process, the revision here specifies "human body tissue" with a cross-reference to the testing procedures.]

* * * * *

9. Section 96.630 is added to read as follows:

§ 95.630 MICS Transmitter ~~frequencies and stability.~~

~~(a)~~ frequency monitoring and stability.

(a) Medical Implant programmer/control transmitters must incorporate a mechanism for monitoring the channel or channels that the MICS system devices intend to occupy. The monitoring system antenna shall be the antenna normally used by the programmer/control transmitter for a communications session. Before a medical implant programmer/control transmitter initiates a MICS communications session, the following access criteria must be met:

1. The monitoring system bandwidth measured at its 20 dB down points must be equal to or greater than the emission bandwidth of the intended transmission.

2. Within 5 seconds prior to initiating a communications session, circuitry associated with a medical implant programmer/control transmitter must monitor the channel or channels the MICS system devices intend to occupy for a minimum of 10 milliseconds per channel.

3. Based on use of an isotropic monitoring system antenna, the monitoring threshold power level must not be more than 10logB(Hertz) -150 (dBm/Hertz) + G(dBi) where B is the emission bandwidth of the MICS communication session transmitter having the widest emission and G is the medical implant programmer/control transmitter monitoring system antenna gain relative to an isotropic antenna. For purposes of showing compliance with the above provision, the above calculated threshold power level must be increased or decreased by an amount equal to the monitoring system antenna gain above or below the gain of an isotropic antenna, respectively.

4. If no signal in a MICS channel above the monitoring threshold power level is detected, the medical implant programmer/control transmitter may initiate a MICS communications session involving transmissions to and from a medical implant device on that channel. The MICS communications session may continue as long as any silent period between consecutive data transmission bursts does not exceed 5 seconds. If a channel meeting the criteria in subparagraph (3) above is unavailable, the channel with the lowest ambient power level may be accessed.

5. When a channel is selected prior to a MICS communications session, it is permissible to select an alternate channel for use if communications is interrupted, provided that the alternate channel selected is the next best choice using the above criteria. The alternate channel may be accessed in the event a communications session is interrupted by interference. The following criteria must be met:

(i) Before transmitting on the alternate channel, the channel must be monitored for a period of 10 milliseconds.

(ii) The detected power level during this 10 millisecond period must be no higher than 6 dB above the power level detected when the channel was chosen as the alternate channel.

(iii) In the event that this alternate channel provision is not used by the MICS system or if the criteria in (i) and (ii) above are not met, a channel must be selected using the access criteria specified in Section 95.630(a)(1) -(4).

6. As used in this section, the following definitions apply:

(i) Emission bandwidth- Measured as the width of the signal between the points on either side of carrier center frequency that are 20 dB down relative to the maximum level of the modulated carrier. Compliance will be determined using instrumentation employing a peak detector function and a resolution bandwidth approximately equal to 1% of the emission bandwidth of the device under test.

(ii) MICS Channel- Any continuous segment of spectrum that is equal to the emission bandwidth of the device with the largest bandwidth that is to participate in a MICS communications session. (Note: The rules do not specify a channeling scheme for use by MICS systems.)

(iii) MICS communications session: a collection of transmissions, that may or may not be continuous between MICS system devices.

(b) MICS communications sessions initiated by a medical implant event are not required to use the access criteria set forth in Section 95.630(a).

(c) Stations may operate on any of the frequencies in the band 402.000 - 405.000 MHz, provided that the out-of-band emissions are attenuated in accordance with the requirements of § 95.635.

~~(b)~~(d) The authorized bandwidth of the emission from a MICS station shall not exceed 300 kHz, and no communications session involving MICS stations shall use more than a total of 300 kHz of bandwidth during such a session. Note: This provision does not preclude full duplex or half duplex communications provided that the total amount of bandwidth utilized by all of the MICS channels employed in such a MICS communications session does not exceed 300 kHz.~~.~~

~~(c) The frequency stability of MICS transmitters shall be sufficient to maintain compliance with the emission limits of § 95.635~~(e) Each transmitter in the MICS service must maintain a frequency tolerance of +/- 100 ppm of the operating frequency over the range:

(1) ~~12(C~~ 25^0C to ~~55(~~45^0 C in the case of medical implant transmitters; and

(2) ~~(2) 0(C~~ 0^0C to ~~70(C~~ 55^0C in the case of medical implant programmer/control transmitters.

(f) The provisions of the section shall not be used to extend the range of spectrum occupied over space or time for the purpose denying fair access to spectrum for other MICS systems.

[Rationale: The MICS band is a valuable resource to be shared by many different users and systems produced by various manufacturers. This revision sets forth a "listen before transmitting" requirement designed to minimize the possibility of interference among MICS systems and to other users of the band. The use of such a technique was envisioned in the ITU-R paper that determined that MICS operations could be compatible with existing users in the band and prove to be a feasible communications service. The concept is also embodied in FCC rules pertaining to other shared services. See, e.g. Section 90.403(e) of the Rules. Although the monitoring requirement will add initially to the complexity of the medical implant programmer/control transmitter, the benefit will be increased compatibility among systems of different manufacturers, more efficient use of spectrum, and greater reliability in the transmission of patient data to and from medical implants.

Similarly, the basic frequency stability requirement set forth above will make for more efficient use of the spectrum resource by controlling more effectively frequency drift within the MICS band. It will also help to make the U.S. regulations more compatible with developing regulations for this use in Europe and Asia.

The proposal to limit the total amount of bandwidth employed in a communications session is intended as a spectrum conservation step. Medtronic expects that because of ambient noise, the full three megahertz of spectrum allocated for MICS operations will, in fact, not be available in most cases. See Appendix B to the MICS Petition for Rule Making showing representative noise measurements. Hence, the need to make efficient use of the spectrum while not precluding flexibility in the modes of operation.

Finally, the change of the temperature range for frequency stability reflects the reality that a medical implant transmitter would never be expected to function over a range in excess of 25° to 45 ° C (77° to 106° F) because this would encompass the expected range of patient viability. Similarly, the range of 0° to 55° C (32° to 131° F) would encompass the expected range of temperatures to which a programmer/control transmitter would likely be exposed. These revised ranges reflect further development work directed at the implementation of spectrally efficient MICS transmitters and more realistically match the expected operating environment extremes. Thus, as development of MICS transmitters has proceeded, it has become apparent that there is no need for maintaining stability over a greater range, particularly in the case of the medical implant transmitter, which must balance every telecommunications performance criterion against the need to conserve precious electrical power supplied by the same battery used for therapeutic and diagnostic purposes.]

10. Section 95.631 is amended by adding paragraph (h) to read as follows:

§ 95.631 Emission types.

* * * * *

(h) A MICS station may transmit any emission type appropriate for communications in this service. Voice communications, however, are prohibited.

11. Section 95.633 is amended by adding paragraph (e) to read as follows:

§ 95.633 Emission bandwidth.

* * * * *

(e) For transmitters in the MICS:

(1) ~~(1)~~ The maximum authorized emission bandwidth is 300 kHz.

(2) ~~(2)~~ Lesser authorized emission bandwidths may be employed, provided that the unwanted emissions are attenuated as provided in § 95.635 and that the ~~average~~ power radiated in any 300 kHz bandwidth does not exceed 25 microwatts EIRP. See ~~§~~§§ 95.605 and 95.639(f) concerning power measurement procedures.

(3) Emission bandwidth shall be determined by measuring the width of the signal between two points, one below the carrier center frequency and one above the carrier center frequency, that are 20 dB down relative to the maximum level of the modulated carrier. Compliance with the emission bandwidth limit is based on the use of measurement instrumentation employing a peak detector function with an instrument resolution bandwidth approximately equal to 1.0 percent of the emission bandwidth of the device under measurement.

[Rationale: These proposed revisions simply clarify measurement procedures and are designed to minimize confusion at the time MICS equipment is tested for certification.]

12. Section 95.635 is amended by revising paragraph (b) and adding paragraph (d) to read as follows:

§ 95.635 Unwanted radiation.

* * * * *

(b) The power of each unwanted emission shall be less than TP as specified in the applicable paragraphs listed in the following table:

Transmitter	Emission type	Applicable subparagraphs
GMRS.....	A1D, A3E, F1D, G1D, F3E, G3E with filtering	(1), (3), (7)
	A1D, A3E, F1D, G1D, F3E, G3E without filtering .	(5), (6), (7)
	H1D, J1D, R1D, H3E, J3E, R3E	(2), (4), (7)
FRS.....	F3E with filtering	(1), (3), (7)
R/C:		
27 MHz	As specified in § 95.631(b)	(1), (3), (7)
72-76 MHz ..	As specified in § 95.631(b)	(1), (3), (7), (10), (11), (12)
CB	A1D, A3E	(1), (3), (8), (9)
	H1D, J1D, R1D, H3E, J3E, R3E	(2), (4), (8), (9)
	A1D, A3E type accepted before September 10, 1976	(1), (3), (7)
	H1D, J1D, R1D, H3E, J3E, R3E type accepted before September 10, 1986	(2), (4), (7)
LPRS	As specified in paragraph (c)	
MICS	As specified in paragraph (d)	

NOTE 1 - Filtering noted for GMRS and FRS transmitters refers to the requirement in § 95.637(b).

NOTE 2 - Unwanted RF radiation may be stated in mean power or in peak envelope power, provided it is stated in the same parameter as TP.

NOTE 3 - Subparagraphs (1), (10), (11), and (12) of this paragraph apply to transmitters operating in the 72-76 MHz band that are manufactured or imported into the United States on or after March 1, 1992, or marketed or sold on or after March 1, 1993. Subparagraphs (1), (3), and (7) of this paragraph apply to transmitters operating in the 72-76 MHz band manufactured or imported into the United States before March 1, 1992, or marketed before March 1, 1993.

NOTE 4 - If spurious or harmonic emissions result in *harmful interference* (any transmission, radiation or induction that endangers the functioning of a radionavagation or other safety service or seriously degrades, obstructs or repeatedly interrupts a radiocommunication service operating in accordance with applicable laws, treaties and regulations), the FCC may, at its discretion, require appropriate technical changes in the station equipment to alleviate the interference, including the use of a low pass filter between the transmitter antenna terminals and the antenna feed line.

(1) At least 25 dB (decibels) on any frequency removed from the center of the authorized bandwidth by more than 50% up to and including 100% of the authorized bandwidth.

(2) At least 25 dB on any frequency removed from the center of the authorized bandwidth by more than 50% up to and including 150% of the authorized bandwidth.

(3) At least 35 dB on any frequency removed from the center of the authorized bandwidth by more than 100% up to and including 250% of the authorized bandwidth.

(4) At least 35 dB on any frequency removed from the center of the authorized bandwidth by more than 150% up to and including 250% of the authorized bandwidth.

(5) At least 83 $\log_{10}$ (f_d/5) dB on any frequency removed from the center of the authorized bandwidth by a displacement frequency (f_d in kHz), of more than 5 kHz up to and including 10 kHz.

(6) At least 116 $\log_{10}$ (f_d/6.1) dB, or if less, 50 + 10 $\log_{10}$ (TP) dB, on any frequency removed from the center of the authorized bandwidth by a displacement frequency (f_d in kHz), of more than 10 kHz up to and including 250% of the authorized bandwidth.

(7) At least 43 + 10 $\log_{10}$ (TP) dB on any frequency removed from the center of the authorized bandwidth by more than 250%.

(8) At least 53 + 10 $\log_{10}$ (TP) dB on any frequency removed from the center of the authorized bandwidth by more than 250%.

(9) At least 60 dB on any frequency twice or greater than twice the fundamental frequency.

(10) At least 45 dB on any frequency removed from the center of the authorized bandwidth by more than 100% up to and including 125% of the authorized bandwidth.

(11) At least 55 dB on any frequency removed from the center of the authorized bandwidth by more than 125% up to and including 250% of the authorized bandwidth.

(12) At least 56 + 10 $\log_{10}$ (TP) dB on any frequency removed from the center of the authorized bandwidth by more than 250%.

* * * * *

(d) For transmitters designed to operate in the MICS, emissions shall be attenuated in accordance with the following:

(1) Emissions more than 250 kHz outside of the MICS band (402.000 MHz - 405.000 MHz) shall be attenuated to a level no greater than the following field strength limits:

Frequency (MHz)	Field strength (μV/m)	Measurement distance (m)
30-88	100	3
88-216	150	3
216-960	200	3
Above 960	500	3
NOTE - In the table above, the tighter limit applies at the band edges.		

(2) ~~(2)~~ The emission limits shown in the above table are based on measurements employing a CISPR quasi-peak detector except that above 1 GHz, the limit is based on measurements employing an average detector. ~~The emission limit above 1 GHz is 5000 uV/m as measured at 3 meters with an average detector.~~ Measurements above 1 GHz shall be performed using a minimum resolution bandwidth of 1 MHz. See also, § 95.605.

(3) ~~(3)~~ The emissions from a MICS transmitter must be measured to at least the tenth harmonic of the highest fundamental frequency designed to be emitted by the transmitter.

4) ~~(4)~~ Emissions within the MICS band (402-405 MHz) more than 150 kHz away from the center frequency of the spectrum the transmission is intended to occupy shall be attenuated below the transmitter output power at least 20 dB~~, except as provided in § 95.635(d)(1).~~ . Compliance with this limit is based on the use of measurement instrumentation employing a peak detector function with an instrument resolution bandwidth approximately equal to 1.0 percent of the emission bandwidth of the device under measurement.

5) Emissions 250 kHz or less above and below the MICS band (402 - 405 MHz) shall be attenuated below the maximum permitted output power at least 20 dB. Compliance with this limit is based on the use of measurement instrumentation employing a peak detector function with an instrument resolution bandwidth approximately equal to 1.0 percent of the emission bandwidth of the device under measurement.

[Rationale: The language proposed to be deleted from paragraph 2, above, appears to have been included in error. The limit above 1 GHz is 500 uV/m at 3 meters as shown in the

table immediately above paragraph 2. The additional proposed provisions in paragraphs 4 and 5 are designed to specify attenuation within the MICS band and immediately above and below the band so as make more efficient use of spectrum. The "mask" should offer designers flexibility while still reducing the possibility of unwanted emissions.]

13. Section 95.639 is amended by adding paragraph (f) to read as follows:

§ 95.639 Maximum transmitter power.

* * * * *

(f) In the MICS the following limits apply:

(1) The maximum EIRP for ~~programmer/control~~ transmitter stations in the MICS ~~is 25 microwatts, provided, however, that the~~ service is 25 uWatts. The antenna associated with ~~the~~ any transmitter in the MICS service must be supplied with the transmitter and shall be considered part of the transmitter subject to ~~the~~ equipment authorization. Compliance of any MICS service transmitter with the 25uWatts EIRP limit may be determined by measuring the radiated field from the EUT at 3 meters and calculating the EIRP. The equivalent radiated field strength at 3 meters when measured on an open area test site for 25 uWatts EIRP is 18.2 mV/meter or 9.1 mV/meter at 3 meters for 25 uWatts EIRP when measured on a test site equivalent to free space such as a fully anechoic test chamber. Regardless of approach, compliance is based on measurements using a peak detector function and measured over an interval of time when transmission is continuous and at its maximum power level. In lieu of using a peak detector function , instrumentation techniques set forth in ANSI C63.17-1998, Section 6.1.2.2.1 or Section 6.1.2.2.2, may be used in determining compliance with the above specifications. ~~The antenna and the transmitter shall be designed to ensure that no antenna other than that furnished by the holder of the equipment authorization for the transmitter shall be used with the transmitter.~~

~~(2) The maximum field strength from an inserted implant transmitter is 9.1 mV/m (rms) at 3 meters as measured with an instrument having a peak detector function. The antenna for a medical implant transmitter must be supplied with the transmitter and shall be considered part of the transmitter subject to the equipment authorization for the transmitter.~~

~~(3) The average~~

(2) For a transmitter intended to be implanted in a human body, the following test fixture must be used to simulate operation of the implant under actual operating conditions. See § 95.605.

a) For measurement purposes to determine compliance with emission limits, the radiating characteristics of an implant transmitter placed in a test fixture should approximate

those of an implant transmitter placed in a human body. An appropriate human torso simulator for testing medical implant transmitters consists of a cylindrical Plexiglas container with a size of 30 cm by 76 cm with a sidewall thickness of 0.635 cm. It must be completely filled with a material that is sufficiently fluidic that it will flow around the implant without any voids. The dielectric and conductivity properties of this material must match the dielectric and conductivity properties of human muscle tissue at 403.5 MHz. All emissions measurements will be made using the above specification at a nominal temperature of 22^0C . Simple saline solutions do not meet the above criteria. A mounting grid for the implant inside the container must be provided that permits the radiating element or elements of the implant to be positioned vertically and horizontally. The grid should also support any additional implant leads associated with the therapeutic function in a fixed repeatable manner. The implant must be mounted 6 cm from the sidewall and centered vertically within the container. The above fixture shall be placed on a turntable such that the implant transmitter will be located at a nominal 1.5-meter height above ground and at a 3-meter distance from the measurement antenna. Radiated emissions measurements shall then be performed to insure compliance with the applicable technical specifications.

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b) A formula for a suitable tissue substitute material is defined in the paper "Simulated Biological Materials for Electromagnetic Radiation Absorption Studies" by G. Hartsgrove, A. Kraszewski, and A. Surowiec as published in "Bioelectromagnetics 8:29-36 (1987)".

(3) The power radiated in any 300 kHz bandwidth shall not exceed 25 microwatts EIRP. See ~~§ 95.633(e)(4).~~§§ 95.633(e) and 95.639(f).

[Rationale: Equipment performance measurement for certification purposes often raises issues in new radio services long after the rule making has concluded. The proposed additions and revisions set forth above represent an effort to reduce the likelihood of such questions, provide greater guidance for manufacturers and reduce the prospect of delays at the time equipment certification applications are prepared and evaluated. With respect to the proposed methods, it should be noted that finite difference time domain modeling analysis for this arrangement when compared to the same modeling analysis performed using the "Visible Human Project" model concludes that this arrangement approximates the RF energy distribution and attenuation characteristics that will be encountered by a MICS system implant in normal operation.]

14. Section 95.649 is amended by revising the text to read as follows:

§ 95.649 Power capability.

No CB, R/C, LPRS, MICS transmitter, or FRS unit shall incorporate provisions for increasing its transmitter power to any level in excess of the limits specified in § 95.639.

15. Section 95.651 is amended by revising the text to read as follows:

§ 95.651 Crystal control required.

All transmitters used in the Personal Radio Services must be crystal controlled, except an R/C station that transmits in the 26-27 MHz frequency band, a FRS unit, a LPRS unit, and a MICS transmitter.

16. APPENDIX 1 TO SUBPART E TO PART 95 - GLOSSARY OF TERMS is revised to read as follows:

The definitions used in part 95, Subpart E are:

Authorized bandwidth. Maximum permissible bandwidth of a transmission.

Carrier power. Average TP during one unmodulated RF cycle.

CB. Citizens Band Radio Service.

CB transmitter. A transmitter that operates or is intended to operate at a station authorized in the CB.

Channel frequencies. Reference frequencies from which the carrier frequency, suppressed or otherwise, may not deviate by more than the specified frequency tolerance.

Crystal. Quartz piezo-electric element.

Crystal controlled. Use of a crystal to establish the transmitted frequency.

dB. Decibels.

EIRP. Effective Isotropic Radiated Power. Antenna input power times gain, expressed in watts, where the gain is referenced to an isotropic radiator.

FCC. Federal Communications Commission.

Filtering. Refers to the requirement in § 95.633(b).

FRS. Family Radio Service.

GMRS. General Mobile Radio Service.

GMRS transmitter. A transmitter that operates or is intended to operate at a station authorized in the GMRS.

Harmful interference. Any transmission, radiation or induction that endangers the functioning of a radionavigation or other safety service or seriously degrades, obstructs or repeatedly interrupts a radiocommunication service operating in accordance with applicable laws, treaties and regulations.

Mean power. TP averaged over at least 30 cycles of the lowest modulating frequency, typically 0.1 seconds at maximum power.

MICS. Medical Implant Communications Service.

Medical implant device. Apparatus that is placed inside the human body for the purpose of performing diagnostic or therapeutic functions.

Medical implant event. An occurrence or the lack of an occurrence recognized by a medical implant device, or duly authorized health care professional, that requires the transmission of data from a medical implant transmitter in order to protect the safety or well-being of the person in whom the medical implant transmitter has been implanted.

[Rationale: As revised, the definition simply recognizes more clearly that the health care professional has the flexibility to determine what, for a particular patient, will be considered a medical implant event. Thus, if, in the medical judgment of a physician or other authorized health care professional, the patient's well-being requires the implant to transmit under certain conditions, the health care professional may program the implant to recognize the conditions, which may include the passage of a preset period of time .]

Medical Implant Communications Service (MICS) transmitter. A transmitter authorized to operated in the MICS.

Medical implant programmer/control transmitter. A MICS transmitter that operates or is designed to operate outside of a human body for the purpose of communicating with a receiver connected to a medical implant device.

Medical implant transmitter. A MICS transmitter that operates or is designed to operate within a human body for the purpose of facilitating communications from a medical implant device.

Peak envelope power. TP averaged during 1 RF cycle at the highest crest of the modulation envelope.

R/C. Radio Control Radio Service.

R/C transmitter. A transmitter that operates or is intended to operate at a station authorized in the R/C.

RF. Radio frequency.

Transmitter. Apparatus that converts electrical energy received from a source into RF energy capable of being radiated.

TP. RF transmitter power expressed in W, either mean or peak envelope, as measured at the transmitter output antenna terminals.

W. Watts.

17. Section 95.1019 is revised to read as follows:

§ 95.1019 Marketing limitations.

Transmitters intended for operation in the LPRS may be marketed and sold only for those uses described in § 95.1009.

18. Subpart H is added to read as follows:

Subpart H - Medical Implant Communications Service (MICS)

§ 95.1101 Eligibility

Operation in the MICS is permitted by rule and without an individual license issued by the FCC. A person is permitted to operate medical implant transmitters connected to medical implant devices that have been implanted in that person by a duly authorized health care professional and medical implant programmer/control transmitters associated with their medical implant transmitter(s). Duly authorized health care professionals are permitted by rule to operate MICS transmitters. Manufacturers of medical implant devices and MICS transmitters and their representatives are authorized to operate transmitters in this service for the purpose of demonstrating such equipment to duly authorized health care professionals. No entity that is a foreign government or which is acting in its capacity as a representative of a foreign government is eligible to operate a MICS transmitter. The term "duly authorized health care professional" means a physician or other individual authorized under state or federal law to provide health care services using medical implant devices. Operations that comply with the requirements of this part may be conducted under manual or automatic control.

§ 95.1103 Authorized locations.

MICS operation is authorized anywhere CB station operation is authorized under § 95.405.

§ 95.1105 Station Identification.

A MICS station is not required to transmit a station identification announcement.

§ 95.1107 Station inspection.

All non-implanted MICS apparatus must be made available for inspection upon request by an authorized FCC representative. Persons operating implanted medical implant transmitters shall cooperate reasonably with duly authorized FCC representatives in the resolution of interference.

§ 95.1109 Permissible communications.

MICS stations may transmit non-voice data as permitted below:

(a) Except as provided below and for the purposes of testing and for demonstrations to health care professionals, medical implant programmer/control transmitters may transmit only operational, diagnostic and therapeutic information associated with a medical implant device that has been implanted by a duly authorized health care professional.

(b) Except in response to a medical implant event, no medical implant transmitter shall transmit except in response to a transmission from a medical implant programmer/control transmitter or a non-radio frequency actuation signal generated by a device external to the body in which the medical implant transmitter is implanted or is to be implanted.

(c) Medical implant programmer/control transmitters may be interconnected with other telecommunications systems including the public switched telephone network.

(d) Medical implant programmer/control transmitters may transmit a during a MICS communications session, as defined in Section 95.630, for the purpose of facilitating MICS system operation for no more than 5 seconds without the communications of data.

(e) Medical implant programmer/control transmitters may not be used to relay information to a receiver that is not included with a medical implant device. Wireless retransmission of information intended to be transmitted by a medical implant programmer/control transmitter or information received from a medical implant transmitter shall be conducted using other radio services that operate in spectrum outside of the MICS band.

[Rationale: The addition of subsection (c) simply recognizes affirmatively that medical implant programmer/control transmitters may be connected to other telecommunications systems including the public switched telephone network. While the lack of a specific prohibition implies that such connection is permitted, the additional language serves to clarify the point. The interconnection capability will prove to be essential in certain telemedicine applications involving remote clinics and in-home care. Subsection (d) has been added to clarify that energy may be transmitted to alert others that the channel is in use for a MICS communications session. Note, however, that if no data are transmitted within 5 seconds, the system must reacquire a channel by following the monitoring provisions of Section 95.630. The addition of subsection (e) is intended to clarify that programmer/control transmitters are not to be used for the transmission of data from one

such device to another. If wireless linking of the medical implant programmer/control transmitters is needed, other spectrum is available for such a use.]

§ 95.1111 Channel use policy.

(a) The channels authorized for MICS operation by this part of the FCC Rules are available on a shared basis only and will not be assigned for the exclusive use of any entity.

(b) Those using MICS transmitters must cooperate in the selection and use of channels in order to reduce interference and make the most effective use of the authorized facilities. Channels must be selected in an effort to avoid interference to other MICS transmissions. See § 95.630.

(c) ~~(c)~~ Operation is subject to the condition that no harmful interference is caused to stations operating in the 400.150 - 406.000 MHz band in the Meteorological Aids, Meteorological Satellite, or Earth Exploration Satellite Services. MICS stations must accept any interference from stations operating in the 400.150 - 406.000 MHz band in the Meteorological Aids, Meteorological Satellite, or Earth Exploration Satellite Services.

[Rationale: Cross-references the monitoring requirements, which are proposed as an interference prevention mechanism.]

§ 95.1113 Antennas.

No antenna for a ~~MICS~~ medical implant programmer/control transmitter shall be configured for permanent outdoor use, provided, however, that any antenna used outdoors shall not be affixed to any structure for which the height to the tip of the antenna will exceed three (3) meters (9.8 feet) above ground.

§ 95.1115 Disclosure polices and registration.

(a) Manufacturers of MICS transmitters must include with each transmitting device the following statement: **"**This transmitter is authorized by rule under the Medical Implant Communications Service (47 C.F.R. Part 95) and must not cause harmful interference to stations operating in the 400.150 - 406.000 MHz band in the Meteorological Aids (i.e. transmitters and receivers used to communicate weather data), the Meteorological Satellite, or the Earth Exploration Satellite Services and must accept interference that may be caused by such aids, including interference that may cause undesired operation. This transmitter shall be used only in accordance with the FCC Rules governing the Medical Implant Communications Service. Analog and digital voice communications are prohibited. Although this transmitter has been approved by the Federal Communications Commission, there is no guarantee that any particular transmission from this transmitter will be free from interference."

(b) The holder of the grant of equipment authorization shall include with each ~~MICS~~ medical implant programmer/control transmitter a notice that the entity responsible for the operation of the ~~MICS~~ medical implant programmer/control transmitter shall, before using the device, register with the holder of the grant of equipment authorization. In the event that control of the device is

transferred, it shall be reregistered in the name of the new entity having responsibility for its operation. The notice may be included with the instruction manual for the device or as a separate enclosure with the device. Such registration shall include the name and mailing address of the entity, the serial number of the medical implant programmer/control transmitter, and a telephone number for the entity that can be ~~use~~ used to notify the entity if interference from the medical implant programmer/control transmitter is suspected. Such registration information shall be maintained by the holder of the grant of equipment authorization for a period of at least ten years and made available, upon request, to the FCC in the event that interference from the device is suspected.

[Rationale: Corrects a typographical error.]

§ 95.1117 Labeling requirements.

(a) Medical implant programmer/controller transmitters shall be labeled as provided in part 2 of this chapter and shall bear the following statement in a conspicuous location on the device:

> This device may not interfere with stations operating in the 400.150 - 406.000 MHz band in the Meteorological Aids, Meteorological Satellite, and Earth Exploration Satellite Services and must accept any interference received, including interference that may cause undesired operation. Prior to initial operation, the entity that will be responsible for the operation of this device must register its name, mailing address, telephone number, and the serial number of this device with [name and address of equipment authorization grantee] as required by the FCC rules.

Note: In lieu of an address for the equipment authorization grantee, a telephone number may be provided. Where such devices are leased, the lessor may provide to the equipment authorization grantee the information required by this section with respect to each lessee.

(b) Where a medical implant ~~programmer/controller~~ programmer/control transmitter is constructed in two or more sections connected by wire and marketed together, the statement specified in this section is required to be affixed only to the main control unit.

(c) Medical implant transmitters shall be identified with a serial number. The FCC ID number associated with the transmitter and the information required by Section 2.925 of the FCC Rules may be placed in the instruction manual for the transmitter and on the shipping container for the transmitter, in lieu of being placed directly on the transmitter.

[Rationale: Corrects the language to use the term of art "programmer/control transmitter."]

§ 95.1119 Marketing limitations.

Transmitters intended for operation in the MICS may be marketed and sold only for those uses described in § 95.1109 of this chapter.